

# MNI CODE OF CONDUCT

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12/04/2022

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## 1 Preamble

The MNI Code of Conduct (the “**Code**”) sets minimum standards for MNI and its Members which are companies providing ingredients, solutions, finished products, medical devices and services for nutritional therapy. The Code is not intended to:

- address or regulate commercial terms and conditions relating to the price, sale and distribution of medical nutrition, procurement, including rental of commercial space, rebates and discounts,
- limit innovation of each Member’s business or
- otherwise align the Members strategic behaviour in the marketplace, which must always be independent and in compliance with applicable laws, industry codes and rules.

All provisions in the Code have the intention to help avoid conflicts of interest, healthcare fraud and abuse as well as corrupt or other illegal activities and to promote a fair competition among MNI members and support ethical and transparent interactions with the Healthcare Community.

## 2 Scope and Applicability of the Code

- The Code applies and sets minimum standards to MNI and all its members (“**Members**”).
- Geographically, this Code shall apply to:
  - activities with the Healthcare Community occurring in the EU, United Kingdom of Great Britain and Northern Ireland, EEA countries and Switzerland.
- The Code is applicable to interactions between MNI and its Members and Healthcare Professionals (“**HCPs**”) and Healthcare Organisations (“**HCOs**”) and Patients and Patient Organisations, in the field of Medical Nutrition Products and Services
- The Code applies as well to interactions with organisations which consist of different interest groups in the field of Medical Nutrition Products and Services that include at least a certain number of HCPs, HCOs, Patients and/or Patient Organisations, so called “**Multi-Stakeholder Organisations**” (“**MSOs**”). For Interactions with MSOs, generally the below rules on interactions with Patients and Patient Organisations (section 3.2) apply, whereas for HCPs and HCOs being members of an MSO, the specific rules for interactions with HCPs/HCOs (section 3.3) apply.
- Medical Nutrition includes specialised products and services for nutritional therapy (“**Medical Nutrition Products and Services**”): Oral Nutritional Supplements, and Enteral Nutrition (tube feeding feeding via the gastrointestinal tract) and other foods for special medical purposes (“**FSMPs**”), and Parenteral Nutrition (intravenous feeding).
- The Code shall not apply to commercial activities as mentioned in the preamble.

- The Code shall not apply to any activities or interactions of MNI and its Members beyond Medical Nutrition Products and Services, such as Breast-Milk Substitutes.

### **3 Guidelines on activities**

#### **3.1 Applicable laws, Codes and Principles of Healthcare Compliance**

All interactions pursuant to this Code shall be subject to applicable laws, industry codes and rules. Where applicable laws, industry codes and rules are stricter than this Code, such other laws, industry codes and rules must be followed.

#### **3.2 Patients, Patient Organisations and Multi-Stakeholder Organisations**

With respect to interactions with Patients and Patient Organisations or Multi-Stakeholder Organisations with MNI and/or its Members, the following shall apply:

- All interactions between Patient Organisations/MSOs and MNI and/or its Members must be based on mutual respect.
- EU and national legislations and codes of practice, prohibiting the advertising of prescription-only nutritional therapies to the general public, apply.
- The communication or promotion of Medical Nutrition Products and Services, to Patients or Patient Organisations/MSOs shall be made only subject to applicable laws, industry codes and rules.
- Written agreements

When MNI or its Members provide significant financial support, significant indirect support and/or significant non-financial support to Patients or Patient Organisations or MSOs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. educational or research grant, specific meeting or publication, etc.). If applicable, it must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support.

- Non interference in activities

MNI and MNI members will not interfere in the activities, deliverables, and content of whatever is produced which should be developed independently by the Patient Organisation/MSO, to the extent that the activities are in line with the written agreement/contract, including the purpose of the use of funds.

- Use of logos and proprietary materials

The public use of a Patient Organisation's/MSO's logo and/or proprietary material by MNI or its Members requires written permission from that Patient

Organisation/MSO. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

- Editorial Control

MNI and its Members must not seek to influence the content of Patient Organisation/MSO material they support in a manner favourable to their own commercial interests. This does not preclude MNI or its Members from correcting factual inaccuracies. In addition, at the request of Patient Organisations/MSOs, MNI or its Members may contribute to the drafting of the text from a fair and balanced scientific perspective.

- Transparency

In order to avoid conflicts of interest, MNI (but not MNI Members) must make publicly available a list of Patient Organisations/MSOs to which it provides financial support and/or significant indirect/non-financial support. This should include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs.

For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the Patient Organisation/MSO receives. This information may be provided on a European level and should be updated at least once a year.

MNI must ensure that its sponsorship is always clearly acknowledged and apparent from the outset.

- Contracted Services

Contracts between MNI or its Members and Patients or Patient Organisations/MSOs under which Patients or Patient Organisations/MSOs provide any type of services to MNI or its Members are only allowed if such services are provided for the purpose of supporting healthcare or research, or educational purposes. It is permitted to engage Patients or Patient Organisations/MSOs for activities such as experts and advisors for services such as participation at advisory board meetings and speaker services. The arrangements that cover consultancy or other services must fulfil all the following criteria, to the extent relevant to the particular arrangement:

- a) A written contract or agreement is agreed which properly specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
- b) A legitimate need for the services has been identified and documented;
- c) The criteria for selecting services are related to the identified need and the persons responsible for selecting the service have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;

- d) The extent of the service is not greater than is reasonably necessary to achieve the identified need;
  - e) MNI or the contracting Member maintains records concerning, and makes appropriate use of, the services;
  - f) The engaging of Patient or Patient Organisations/MSOs is not an inducement to recommend a particular product/Service;
  - g) The compensation for the services is reasonable and appropriate;
  - h) In their written agreements/contracts with Patients or Patient Organisations/MSOs, MNI and its Members are encouraged to include provisions regarding an obligation of the Patient or Patient Organisation/MSO to declare that they have provided paid services to MNI or its Members whenever they write or speak in public about a matter that is the subject of the agreement
- Exclusive MNI Member funding
 

No MNI Member may require that it be exclusive funder of a Patient Organisation/MSO or any of its major programs.
  - For sponsoring of Patient Organisation/MSO events, please refer to sec. 3.3.5.

### 3.3 HCP and HCO Interactions

#### 3.3.1 HCP/HCO services and consultancy

- MNI or its Members may engage HCPs and HCOs to provide necessary services.
- In all cases, MNI or its Members must have a legitimate need for the service and shall only pay a reasonable and appropriate fee.
- The HCP or HCO must only be selected and engaged as service providers based on their qualifications and expertise.
- An engagement must not be offered or entered into with the intention to induce the HCP or HCO to purchase, supply, dispense, promote or prescribe a particular product or service.
- All engagements, regardless of extent, must be confirmed in writing or contract, with a clear description of the services and the compensation.
- In addition, the HCP must obtain employer approval where required and, if not, whenever possible, be required to disclose the engagement to the HCP's employer.
- Payment shall only be made for work performed.

### 3.3.2 Meetings hosted by MNI and/or its Members and hospitality

- Meetings between MNI and HCPs and/or HCOs or between MNI Members and HCPs and/or HCOs may facilitate beneficial and essential interactions amongst them.
- Meetings may be held for legitimate educational, scientific or research purposes. Reasonable hospitality may be provided in connection with such meetings.
- Location

A meeting should be held in a location that makes the most logistical sense in light of the location of the attendees or resources necessary for the meeting. This could include major transport hubs and cities with appropriate infrastructure. Locations primarily known for their touristic or recreational character are prohibited.

- Venue

Venues must be appropriate and conducive to the main purpose of the meeting. Appropriate venues may include clinical, laboratory, educational, conference or healthcare settings, or business locations such as business hotels or conference centres. Extravagant venues are never appropriate.

- Hospitality

Subject to applicable laws, industry codes and rules MNI and its Members may provide hotel accommodation, meals and drinks in connection with a meeting, as long as such hospitality is necessary, incidental, reasonable, and secondary to the main purpose of the meeting. Hospitality must be appropriate, reasonable and proportionate, and may only be extended to the persons who qualify as participants in their own right.

- Travel

Travel should always be on the most direct and logical route, taking into account costs to MNI or its Members. Stop-overs, side trips and trip extensions funded or facilitated by MNI or its Members are prohibited. Arrival and departures should, whenever logistically possible, coincide with the beginning and end of the meeting. Flights should be booked in economy class; business class may only be compensated in exceptional circumstances or for longer distance flights, if justified. Guests, spouses, family members, or friends of the HCP may not receive any travel benefit.

### 3.3.3 Educational support

MNI and its Members may support scientific, professional education in the communities they serve. By inviting and funding HCPs to meetings and conferences,

MNI and its Members contribute to the advancement of scientific knowledge and the improvement of Patient care. MNI or its Members may provide educational support by paying registration costs, travel and accommodation and reasonable hospitality.

- Types of Events

Subject to applicable laws, industry codes and rules, MNI and its Members may support HCPs to attend company-organised and hosted events, as well as recognised third party conferences and congresses provided that the events have material scientific, educational and professional content, and relate to areas in which the HCP currently practices and are directly related to the area of Medical Nutrition.

- Invitees

Appropriately qualified HCPs may be invited to events and conferences and receive hospitality and travel support.

Guests, spouses, family members, or friends of the HCP may not be invited to events and conferences.

The decision about who shall receive educational support shall be based on objectively defined criteria that are directly related to the educational needs of the recipient and the educational value of the program.

#### 3.3.4 Site visits

Visiting and touring a Member's manufacturing and R&D facilities helps the HCP to better understand the efficacy and quality of a Member's products and operations.

Visits to a Member's facilities must have scientific or educational value and may never be provided as a means of improperly influencing an HCP.

An HCP should only ever be taken to visit the most relevant site that can demonstrate the capabilities that is crucial to the educational objectives.

All site visits must have a specific and full agenda and should be limited in duration.

#### 3.3.5 Sponsorship of events

Subject to applicable laws, industry codes and rules, MNI and its Members may provide financial sponsorship to third-party organisations for events directed at HCPs.

As a consideration for their support, they will receive commercial advertising opportunities such as booth or exhibit space, etc.

MNI and its Members must ascertain that the sponsored funds will only be used for the stated purpose.

MNI and its Members must not use sponsorship as a way to indirectly fund or support any activity that they could not legitimately undertake themselves.

MNI or its Members must not provide sponsorship that funds or subsidizes recreational or entertainment activities for HCPs.

### 3.3.6 Educational material and inexpensive gifts

MNI and its Members may occasionally provide educational materials, and inexpensive gifts to a HCP in accordance with applicable laws, industry codes and rules in the relevant country.

All such items must be relevant to a HCP's professional duties and ultimately benefit Patients, Patient care or the practice of medicine or pharmacy. Such items should never provide a personal benefit to a HCP and must never be provided as a means of improperly influencing the HCP.

Items that could be easily resold or used to generate income are also prohibited. Gifts must not be given in the form of cash or cash equivalents.

### 3.4 Samples

Medical nutrition product samples provided to an HCP or HCO can be given in reasonable quantities. Samples should not be used for the personal benefit of an HCP or his/her staff or re-sold by the recipient. Medical nutrition samples that do not require a prescription can also be provided to Patients in reasonable quantities. If required locally, samples must be marked "free sample" or "not for sale".

### 3.5 Promotional material and information

Subject to applicable laws and rules, all promotional materials and information related to Medical Nutrition Products (whether printed, digital or oral) must be clear, legible, accurate, up-to-date, balanced, fair, and sufficiently complete to enable the recipient to form his or her own opinion.

Materials and information must comply with applicable laws, industry codes and rules in every country in which they are used or disseminated.

### 3.6 Educational Grants and Research

Subject to applicable laws and rules, MNI and/or its Members may provide Restricted Educational Grants for the advancement of genuine medical education and/or Research Grants to support third party-initiated research studies for clinical or non-clinical research program in Medical Nutrition and/or therapeutic areas in which MNI and/or its Members are interested and/or involved.

Educational Grants may be provided for the following (non-exhaustive) purposes or in the following forms:

- a) Support for third party organised educational events
- b) Support for HCP attendance and/or participation at third party organised educational events as specified in Sec. 3.3.3 through their affiliated HCO or other qualified institution in the Healthcare Community
- c) Scholarships and Fellowships to support advancement of genuine medical education of HCPs;
- d) Grants for public awareness campaigns.

With respect to Educational and/or Research Grants the following shall apply:

- Educational/Research Grants shall not be offered or given with the intention to induce the HCO, Patient, Patient Organisation/MSO or HCP to purchase, supply, dispense, promote or prescribe a particular product or service.
- All Educational and/or Research Grants must be triggered by a written and unsolicited request from an HCO, Patient Organisation or MSO and/or qualified institution, including a detailed description of the purpose/object and value of the activity or documented initiative from MNI and/or its Members containing sufficient information to enable MNI and/or its Members to objectively evaluate the request. In addition, for Research Grants, the request must detail, as a minimum, the type, nature and objective of the research activity, relevant milestones, the approximate duration of the research, and where applicable, the requirements for ethics committee, regulatory and/or other authorizations or approvals.
- Educational and/or Research Grants shall not be provided in response to requests made by an individual HCP.
- All arrangements concerning Educational and/or Research Grants must be recorded in an agreement between MNI and/or its Members and the HCO, Patient Organisation or MSO and/or qualified institution in advance with clear and detailed description of the intended purpose of the Educational and/or Research Grants, entitlements and obligations. In addition, MNI and/or its Members shall ensure that the agreement includes the right to verify that industry contribution is in fact used for the agreed intended purpose.

- Educational Grant for Scholarship and/or Fellowship can only be provided to the HCO, Patient Organisation, MSO where the HCP is in training and/or working. Similarly, MNI and/or its Members shall not have any involvement in any way in the selection of the HCPs who will benefit from the Educational Grant and this shall be reflected in the written agreement between the MNI and/or its Members and the recipient HCO, Patient Organisation or MSO.
- Research Grants may include in kind or financial support for legitimate, study-related, documented expenses or services, and/or reasonable quantities of single-use and/or multiple-use free of charge product(s) for the limited duration of the research.
- MNI and/or its Members shall implement an independent decision-making and review process to identify, prevent and mitigate potential bribery and corruption risks arising in connection with the provision of Educational and/or Research Grants to a specific prospective recipient.

### 3.7 Social contributions

Contributions may be provided to legitimate bona fide entities such as recognised charities, civic organisations and not-for-profit institutions, but never to natural persons. Contributions can take the form of financial and in-kind donations for philanthropic purposes such as supporting scientific research, medical education, Patient education, Patient access to healthcare, and the overall development of healthcare systems. MNI and its Members may also support community and charitable initiatives.

Contributions must be supported by an unsolicited and independent request from the institution, including a detailed description of their needs, the program or project, and the budget.

Contributions should never be given to improperly influence purchasing decisions.

## 4 Antitrust Statement

The Medical Nutrition International Industry association (“**MNI**”) and its members shall not enter into any discussion, activity or conduct that may infringe, on the association’s part or on the part of its members, any applicable competition law. By way of example, members shall not use any meetings of the entire group or smaller gatherings, including formal and informal meetings, as a forum to discuss, communicate, exchange or coordinate on, any commercially sensitive information, including information relating to prices, marketing and advertising strategy, costs and revenues, trading terms and conditions with third parties, including purchasing strategy, terms of supply, trade programs, research, innovation and development or distribution strategy.

## 5 Privacy & the GDPR

If processing personal data received from, collected about or concerning Healthcare Professionals, Healthcare Organisations, Patients and Patient Organisations/MSOs, applicable data protection laws must be complied with. Any disclosure must be compatible with data privacy legislation.

## 6 Definitions

### Enteral Tube Feeding

Enteral Nutrition is administered into the gastrointestinal tract via a nasogastric, nasoenteric or percutaneous tube. Enteral Tube Feeding is required when a Patient is unable to consume sufficient nutrition via the oral route. Examples include severe cystic fibrosis, cerebral palsy, after a stroke or major surgery, such as head and neck surgery, and critical illness.

Enteral Tube Feeding can be supplementary to oral intake or parenteral nutrition, or can be the sole source of nutrition.

### Entertainment

Entertainment includes, but is not limited to, dancing or arrangements where live music is the main attraction, sight-seeing trips, theatre excursions, sporting events (e.g. skiing, golf or football match) and other leisure arrangements. For the avoidance of doubt, incidental, background music shall not constitute Entertainment.

### Educational Grants

Educational Grants means provision of financial support, MNI Members' products or third party products or other in kind support to a HCO, Patient Organisation or MSO by or on behalf of MNI and/or its Members on a Restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, Patients and/or the public on clinical, scientific and/or healthcare topics relevant to Medical Nutrition Products and Services. **"Restricted"** in the context of Grants means that MNI and/or its Members shall specify the intended purpose of the Educational Grant in the Grant agreement, that the Grant support shall not be used for other purposes and that MNI or a Member also shall secure the contractual right to enable it to verify that the Grant is in fact used for the agreed intended purpose.

### Scholarships and Fellowships

Scholarships and Fellowships means Educational Grants provided to a Healthcare Organisation by or on behalf of MNI or a Member to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g.

medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.

### **Healthcare Professionals**

Healthcare Professionals (HCPs) means any natural person that is a medical doctor, a member of medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of Healthcare Professional includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, dispense, purchase or administer medicinal products and (ii) any employee of a pharmaceutical or a nutritional company whose primary occupation is that of a practising Healthcare Professional, but excludes (x) all other employees of a pharmaceutical or a nutritional company and (y) a wholesaler or distributor of medicinal products.

### **Healthcare Community**

Healthcare Professionals, Healthcare Organisations, Patients and Patient Organisations/MSO.

### **Healthcare Organizations**

Healthcare Organizations (HCOs) means any entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society or (ii) through which one or more Healthcare Professionals provide healthcare services. For the avoidance of doubt, wholesalers, distributors, and similar commercial intermediaries are not considered Healthcare Organisations.

### **Home Parenteral Nutrition**

Home parenteral nutrition (HPN) is defined as parenteral nutrition administered outside the hospital, either at home or at nursing home.

### **Medical Nutrition Products and Services**

Medical nutrition encompasses specialised products for nutritional therapy: Oral Nutritional Supplements, Enteral Tube Feeding (via the gastrointestinal tract), and Parenteral Nutrition (intravenous feeding).

Medical Nutrition helps Patients of all ages to address nutritional insufficiencies arising from a disease, disorder or condition, when they are unable to meet their requirements via normal foods.

Medical Nutrition products are to be used under medical supervision. Depending on the situation medical nutrition may be required for short or long term or even for life and may be administered in diverse healthcare settings or at home.

## **Multi-Stakeholder Organisations**

Multi-Stakeholder Organisations (MSOs) means organisations which consist of different interest groups in the field of Medical Nutrition Products and Services that include at least a certain number of HCPs, HCOs, Patients and/or Patient Organisations.

## **Oral Nutritional Supplements**

Oral Nutritional Supplements (ONS) provide macronutrients and micronutrients and are designed to be consumed orally. ONS are available as ready-to-drink liquids or powders that can be prepared as drinks (also called 'sip feeds') but are also available in pre-thickened form.

They may be suitable as a sole source of nutrition but are most commonly used as a supplement to normal foods.

ONS are an effective and non-invasive solution to tackle Disease Related Malnutrition in Patients who are typically able to consume some normal food, but not enough to meet all of their nutritional needs. ONS are effective in a large number of diseases and their treatment – including cancer, stroke, neurological and gastrointestinal conditions, and surgery.

## **Parenteral Nutrition**

Parenteral Nutrition also known as '**intravenous feeding**' - is a method of getting nutrition directly into the blood circulation, bypassing the gastrointestinal tract. Parenteral Nutrition is delivered via a catheter inserted into a peripheral or central vein. Parenteral Nutrition is needed when a Patient is unable to obtain sufficient nutrition through normal food, ONS or tube feeding. For instance indications for Parenteral Nutrition include gastrointestinal failure which can occur after surgery or in critically ill patients, short bowel syndrome, intestinal obstruction, a fistula in the gastrointestinal tract, cancer patients with severe mucositis or premature infants.

## **Patients**

A Patient is any person seeking health care services. The Patient is most often ill or injured and in need of treatment by a physician, nurse, psychologist, dentist, or other health care provider.

## **Patient Organisations**

Patients' organisations are defined as not-for profit organisations which are Patient focused, and in which Patients and/or carers (the latter when Patients are unable to represent themselves) represent a majority of members in governing bodies.

## **Research Grants**

Research Grants means the provision by or on behalf of MNI and/or its Members of funding, products/equipment and/or in kind services to an HCO, Patient Organisation or MSO and/or other qualified institutions that conducts research which is made for the sole restricted purpose of supporting the development or furtherance of bona fide, scientifically valid and legitimate research by the recipient the purpose of which is to advance medical, scientific and healthcare knowledge, medical technologies and/or clinical techniques designed to improve Patient outcomes, each in the area of Medical Nutrition Products and Services.

*This Code shall be reviewed periodically.*

*This Code can only be changed unanimously by MNI Members.*

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<sup>i</sup> European Medicines Agency, Stakeholders and Communications Division, (June 2014). Available at [https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/criteria-be-fulfilled-patient-consumer-healthcare-professional-organisations-involved-european\\_en.pdf](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/criteria-be-fulfilled-patient-consumer-healthcare-professional-organisations-involved-european_en.pdf)